

in the above-referenced application. In connection with this notice, please charge \$330.00 or the sum required under 37 C.F.R. §1.17(b) to Deposit Account No. 19-1025.

RESPONSE

Claims 1, 3, 5-10, 19, and 20 are pending in the application.

In the Office Action of July 17, 2003, the Examiner stated that “[t]he rejection of Claims 1, 3, 5-7, 9, and 10 under 35 U.S.C 103(a) as being unpatentable over Black in view of Patel *et al.*, Guess *et al.*, and Bagchi *et al.* is maintained.” (page 2, paragraph 4). Thus, the Examiner’s rejections depend upon the combination of *all four* of these references. These rejections are respectfully traversed for the following two reasons.

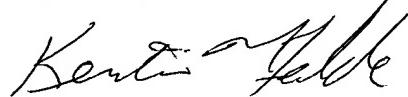
First, as stated in MPEP §2145X.D.2, “[i]t is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).” The Examiner is correct in stating that “[t]he Patel *et al.* patent describes a wide variety of formulations for solid carriers of drugs (See Abstract). Patel *et al.* teaches that various hydrophobic drugs ... may be used in the disclosed solid carriers ... (See Column 5, lines 1-23).” (page 3, 2nd full paragraph).

However, when describing prior-art micronization methods for enhancing *in vivo* performance of hydrophobic pharmaceuticals, Patel et al. states that “[t]hese approaches suffer from several disadvantage., [sic]. Micronization/nanonization presents processing and stability challenges, as well as dissolution limitations, since the micronized/nanosized drug still possesses a high degree of crystallinity.” (column 1, lines 27-31). In contrast, Bagchi et al. states that “[w]e have discovered a novel process of producing micronanoparticulate dispersions that can be precipitated to form dispersions with average particle diameters up to less than 10 nm, for highly enhanced bioavailability.” (column 3, lines 19-22). Patel et al. therefore teaches that micronization should be avoided, while micronization is actually the invention disclosed in Bagchi et al. Thus, these two references teach away from each other, and therefore are not properly combinable. Consequently, the Examiner’s rejections, which depend upon the combination of these two references, cannot stand.

Second, as stated in MPEP §2145X.D.1, “[a] prior art reference that ‘teaches away’ from the claimed invention is a significant factor to be considered in determining obviousness ....” Bagchi et al. also teaches that pharmaceutical agents having “highly enhanced bioavailability ... are derived by chemical attachment of pharmaceutically useful chemical compositions (PUCC) to photographic coupler molecules ....” (column 3, lines 22-25). If a coupler molecule were attached to valdecoxib as taught by Bagchi et al., the resulting molecule would not be valdecoxib, but rather would be a molecule comprising valdecoxib as a moiety. In contrast, claim 1 requires the claimed composition to contain “valdecoxib,” and does not encompass valdecoxib attached to such a coupler molecule. Thus, Bagchi et al. also teaches away from the present invention, and the Examiner cannot properly rely upon this reference to support his rejections.

In view of the foregoing, allowance of the application is respectfully requested.

Respectfully submitted,



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Enclosures

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